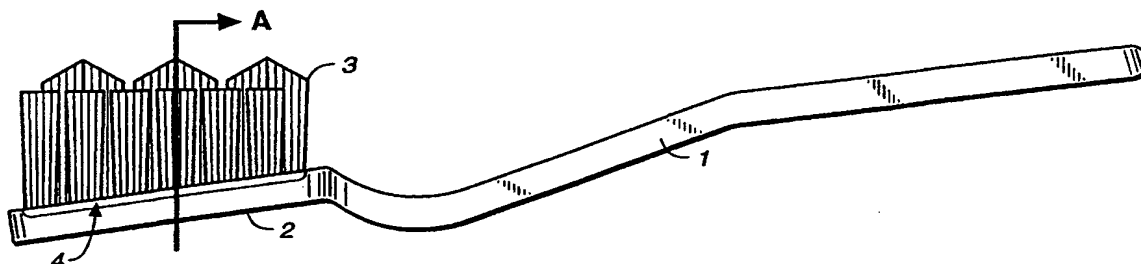


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(54) Title: AN ACCELERATED METHOD AND INSTRUMENTATION FOR WHITENING TEETH



(57) Abstract

A toothbrush for whitening teeth comprising a handle (1) and a head (2). The head (2) contains bristles (3) and a compartment (4) for the insertion of a removable fabric or gel foam containing a catalytic activator. A bleaching agent is applied to the head (2) or bristles (3) in such a manner that accelerated bleaching of the teeth occurs.

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AN ACCELERATED METHOD AND INSTRUMENTATION
FOR WHITENING TEETH

5 FIELD OF THE INVENTION

The present invention relates to the field of dentistry, and specifically to the whitening of the teeth.

BACKGROUND OF THE INVENTION

10 Teeth generally become more darkly pigmented with age and exposure to such materials as tea and coffee, and it has long been a goal of dentistry to provide a means to safely and effectively reverse this darkening process. Historically there are two approaches to the problem.
15 The first involves removing pigmentation that has adhered onto the surface of the teeth. This is commonly achieved through the use of abrasives, sometimes augmented with solvents. While rapidly effective, these techniques have the disadvantage of only being able to remove extrinsic
20 stains, leaving all internal pigmentation unchanged. Thus the whitening effect is extremely limited.

A more recent innovation involves a method of using oxidizing agents to penetrate into the tooth structure and bleach out the undesired pigmentation. The
25 active agents are usually either weak solutions of hydrogen peroxide or carbamide peroxide, which is more stable than hydrogen peroxide.

While effective on both extrinsic and intrinsic discolorations, one major problem encountered with this
30 second approach is the enormous amount of treatment time needed to gain adequate penetration of the tooth structure by the whitening agent. At present, the method

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of application of the whitening agent utilizes either custom or stock trays that are shaped to hold the bleaching agent against the teeth to be whitened. These trays are then filled with the peroxide, and worn for
5 long periods of time, sometimes even overnight. After a series of lengthy treatments, the teeth will usually begin to show the desired whitening effect. The length of these treatments can be discouraging and increases the cost. It is therefore desirable to find a method to more
10 rapidly whiten the teeth.

SUMMARY OF THE INVENTION

In one embodiment, the invention provides a composition whitening teeth, using an effective amount of a bleaching compound and a catalytic activator, where the
15 catalytic activator catalyzes the reaction of a significant portion of the bleaching compound within ten minutes.

In a second embodiment, the invention provides a method for whitening teeth consisting of providing a
20 bleaching compound, providing a catalytic agent, and combining the bleaching agent with the catalytic agent so that a reaction of a significant portion of the bleaching agent occurs within ten minutes.

In another embodiment, the invention provides a
25 device for whitening teeth, consisting of a toothbrush with a head and a handle, where the head has a plurality of bristles, and at least one of the bristles contains a catalytic activator. The handle of this device has a reservoir for a bleaching compound and a means for
30 dispensing the bleaching compound.

In a further embodiment, the invention provides a device for whitening teeth, consisting of a toothbrush with a head and a handle, where the head has an

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applicator and a catalytic activator capable of catalyzing the reaction of a bleaching compound applied to the head.

BRIEF DESCRIPTION OF THE DRAWINGS

5 FIG. 1 shows a side view of a toothbrush made in accordance with the present invention that has a compartment for a catalytic activator on the head.

FIG. 2 is a front elevational view thereof .

10 FIG. 3 shows a cross section of a toothbrush with bristles containing a catalytic activator.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

All publications mentioned herein are incorporated herein by reference for the purpose of describing and disclosing the equipment, compositions, and methodologies
15 which are described in the publications which might be used in connection with the presently described invention.

The invention provides a composition for whitening teeth, consisting of a therapeutically effective amount
20 of a bleaching compound and a catalytic agent, where the catalytic agent is capable of catalyzing the reaction of a significant portion of the bleaching compound within a short period of time. A "bleaching compound" is any compound which has the ability, when activated by a
25 catalyst, of whitening the teeth. Examples of suitable bleaching compounds include an oxygen radical generating agent such as metal ion free peroxides, organic peroxides, and metal ion containing peroxides. Specific, non-limiting examples of bleaching agents suitable for
30 use with the subject invention are carbamide peroxide, carbamyl peroxide, sodium percarbonate, perhydrol urea, and hydrogen peroxide. By "therapeutically effective amount" is meant the quantity of a the bleaching agent,

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when placed in contact with a catalyst according to the invention, necessary to whiten the teeth of a subject. A subject is any mammal, preferably a human.

Typically the bleaching agent employed in the composition in amounts so that about 3% to 40% by weight comprises the bleaching agent. Preferably, if the bleaching compound is hydrogen peroxide, the concentration of the bleaching compound is from about 3 to 12% by weight. Most preferably, if the bleaching agent is hydrogen peroxide, the concentration of the bleaching compound is from about 6% to about 10% by weight. Preferably, if the bleaching agent is carbamide peroxide, carbamyl peroxide, sodium percarbonate, and perhydrol urea, the concentration of the bleaching compound is from about 10% to about 40% by weight. More preferably, if the bleaching agent is carbamide peroxide, carbamyl peroxide, sodium percarbonate or perhydrol urea, the concentration of the bleaching compound is from about 20% to about 30% by weight.

Assays to determine a therapeutically effective amount of a bleaching compound are known in the art. For example, stained extracted teeth can be used to measure a whitening effect (see Example 1). Other assays, such as an analysis of the effect of a bleaching compound on the soft tissues, may also be used in the determination of a therapeutically effective range of concentrations of a bleaching compound.

The bleaching agent is contained in a vehicle; formulations of vehicles for bleaching agents are well known in the art. The formulation can be aqueous or non-aqueous. As an example, glycerin, and polyethylene glycol in combination with water are useful in formulating the vehicle. Thickening or gelling agents

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may also be used in the formulation of the bleaching agent. In one example poloxyethylene/polyoxypropylene block copolymers can be utilized. As another example, carbopol polymers can be used. These polymers are well known in the art, and are available commercially.

The composition of the subject invention further consists of a catalytic agent. A "catalytic agent" is a compound or molecule which accelerates the whitening action of the bleaching compound without being consumed in the reaction. In a preferred embodiment, the catalytic agent accelerates the release of oxygen radicals from an oxygen radical generating agent. Examples of such agents include, but are not limited to activated charcoal, platinum, platinum salts, copper, copper salts, palladium, palladium salts, silver, and silver salts. In a preferred embodiment, activated charcoal is used as the catalytic activator. Of particular use with the subject invention is the commercially activated charcoal Centaur, produced by Calgon, Inc. Catalytic agents useful with the subject invention catalyze the reaction of a significant portion of the bleaching compound within a short period of time of coming into contact with the bleaching compound. By "short period of time" is meant in minutes, preferably about ten minutes or less. The catalytic agent may catalyze the reaction of substantially all of the bleaching compound in about ten minutes of coming into contact with the bleaching agent. In one embodiment the catalytic activator catalyzes the reaction of 50% of the bleaching agent, preferably 70% of the bleaching agent, and more preferably 90% of the bleaching agent. Contact of the bleaching compound with the catalytic agent causes the visible evolution of gas within two minutes of

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contact. "Visable evolution" of a gas, such as oxygen, formed by the contact of the bleaching compound with the catalytic agent can be noted in many ways, such as the formation of bubbles or any sign of gaseous release.

5 In one embodiment, an abrasive material can be used with the composition of the invention. For example a dicalcium phosphate abrasive may be incorporated into the composition (e.g., see U.S. Patent 5, 171, 564). Example of dicalcium phosphate abrasives include, but are
10 not limited to dicalcium phosphate dihydrate, anhydrous dicalcium, or calcium pyrophosphate. Other abrasives of use with the subject invention include siliceous materials. Examples of such materials include, but are not limited to, silica abrasives, such as precipitated
15 amorphous hydrated silica, and alumina abrasives, such as alumina trihydrate, aluminum silicate, calcined alumina, and bentonite.

When an abrasive material is included the vehicle may contain water, humectant, surfactant, and a
20 thickener. Examples of humectants are glycerin, sorbitol, and polyethylene glycol (molecular weight 200-1000). Both mixtures of humectants and single humectants can be employed in the composition of the invention. Thickeners may be incorporated in the abrasive component
25 such as natural and synthetic gums such as carrageenan, xanthan gum, sodium carboxymethyl cellulose, starch, polyvinylpyrrolidone, hydroxyethylpropylcellulose, hydroxybutyl methyl cellulose, hydroxypropyl methyl cellulose, and hydroxyethyl cellulose.

30 In another embodiment, an agent for administering fluoride, such as a fluorine providing salt, which has activity against cavities, may be incorporated into the composition of the subject invention. Such materials are

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characterized by their ability to release fluoride ions in water. Agents for administering fluoride include, but are not limited to, inorganic metal salts such as sodium fluoride, potassium fluoride, and tin fluoride such as
5 stannous fluoride or stannous chlorofluoride, sodium fluorosilicate, ammonium fluorosilicate, and sodium monofluorophosphate.

The composition may also include palliative ingredients for periodontal tissues. Examples of such
10 ingredients include, but are not limited to aloe, eugenol, and vitamin E. Pigments, sweeteners, colors, and flavors may also be incorporated into the composition. The composition may further include an ingredient to decrease tooth sensitivity, such as
15 potassium nitrate. The addition of these components to dental creams, such as toothpaste, are well known in the art.

The invention further provides a method for whitening teeth, by providing a bleaching agent,
20 providing a catalytic agent, and then combining the bleaching agent with the catalytic agent, such that the catalytic agent catalyzes the reaction of a significant portion of the bleaching agent within about ten minutes of combining the bleaching agent with the catalytic
25 agent.

Any convenient means can be utilized for separating the bleaching agent from the catalytic agent prior to the reaction process. In one embodiment, separate containers are used, one of which holds the
30 bleaching agent in liquid form, and one of which holds the catalytic agent in solid or liquid form. The bleaching agent is then mixed with the catalytic agent immediately prior to use. For example, the bleaching

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agent can be in a liquid form, similar to a mouthwash. The catalytic agent can be in the form of a solid powder, contained in a foil packet. Just prior to use, the catalytic agent is added to the liquid containing the
5 bleaching agent and the liquid is retained in the mouth, similar to a mouthwash, for three to five minutes.

In another embodiment, a single container can be compartmentalized so the bleaching agent is housed separately from the catalytic agent. Upon extrusion from
10 the dual compartment container the bleaching agent is combined with the catalytic agent. For example, the whitening agent and catalytic agents can each be contained in a gel or paste form. Upon extrusion from the container, the two are admixed, and placed on a
15 toothbrush. Brushing for three to five minutes can also result in mixing the catalytic agent with the bleaching agent.

In another embodiment, a stable composition is formed consisting of the catalyst microencapsulated and
20 mixed with the bleaching agent. Techniques for microencapsulation of individual components for tooth and gum dentifrice are well known in the art (see U.S. Patent 5,403,578). The encapsulated material is stable until contacted with water. In this embodiment it is preferable
25 for the base composition of the paste to be free of water. Upon use of the composition, and the addition of water, the bleaching agent is placed in contact with the catalyst.

Either a paste or gel containing the bleaching
30 agent and the catalyst may be prepared. Alternatively, a fabric embedded with the bleaching agent and the catalyst can be produced. Upon the addition of water,

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thereby wetting the fabric, the bleaching agent and the catalyst are admixed.

In another embodiment, the catalytic agent can be applied on a solid surface, such as a dental tray (e.g., U.S. Patent 4,990,089). The dental tray can be either pre-fabricated or customized. In order to produce a customized dental tray, a sheet of moldable plastic is used that will conform to a mold of an individual's teeth. Production of such trays is well known in the art. In brief: (1) a mold of the teeth to be whitened is prepared, (2) a sheet of plastic material of a appropriate size between 0.01 inch and 0.1 inch thick is obtained, (3) the plastic sheet is placed in a holder, and, if desired, silicone may be sprayed onto the plastic sheet, (4) the plastic sheet is heated until it becomes malleable, (5) the heated sheet is placed over the model, (6) the heated plastic is contoured to the mold, either manually or using a vacuum process, (7) the mold is removed, and (8) the plastic is trimmed. The catalytic agent may be embedded into a sponge which is inserted into the heated plastic. Alternatively, the catalytic agent can be embedded in a fabric which is bonded to the tray after the plastic has cooled. The catalytic agent can also be directly applied or bonded to the surface of the tray to the cooled plastic, such as by spraying the tray with a solution of copper salts. The bleaching agent is applied to the tray in the form of a paste or a liquid immediately prior to use, and the tray is then applied to the subject's teeth.

In another embodiment, the catalytic agent may be applied to the surface of a toothbrush. A "toothbrush" is a device designed for cleaning teeth that has a region for holding, such as a handle, and a region for cleaning,

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such as bristles or a sponge. The toothbrush is either manually or mechanically agitated to clean the teeth of a subject. The head of the brush can be made of any appropriate material, such as plastic, and can be
5 designed to contain the catalyst, either by applying the catalytic agent directly to the head of the brush, either on the same side of the brush as the bristles or sponge, or on the opposite side of the brush. The catalytic agent can be embedded in a fabric that is bonded to the
10 head of the brush, or the fabric embedded with the catalytic agent can be inserted into a compartment in the head of the brush.

Referring to FIG. 1 there is shown a toothbrush, comprising a handle (1) and a head (2). The head (2)
15 comprises bristles (3) and a compartment (4) for the insertion of a fabric or gel foam comprising a catalytic agent. The fabric or gel foam comprising the catalytic agent may be removed and replaced with a new piece of fabric or gel foam comprising a catalytic agent when
20 desired.

A front elevational view of the device shown in FIG. 1, where a section is shown looking in the direction of (A), is depicted in FIG. 2. Referring to FIG. 2 it can be seen that the compartment (4) in the head of the
25 brush is open to the upper surface of the brush. The bleaching compound is applied to the bristles prior to use of the toothbrush by the subject; the application of the bleaching compound to the toothbrush results in the catalyst contacting the bleaching compound. The subject
30 then uses the toothbrush to brush the teeth, and the whitening effect is thereby achieved.

Alternatively, the bristles located on the head of the tooth brush can be designed to contain the catalyst:

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the catalyst can be applied to the surface of the bristle or it can be embedded into one or more of the bristles of the brush. Referring to FIG. 3, there is shown a toothbrush with a handle (5) and a head (6) with bristles (7). One of the of the bristles (8) is embedded with a catalytic agent. It should be noted that any number or conformation of bristles can be embedded with the catalytic agent. The bleaching compound is applied to the bristles prior to use of the toothbrush by the subject;

10 the application of the bleaching compound to the toothbrush results in the catalyst contacting the bleaching compound. The subject then uses the toothbrush to brush the teeth, and the whitening effect is thereby achieved.

15 The following examples are intended to illustrate but not to limit the invention in any manner, shape, or form, either explicitly or implicitly. While they are typical of those that might be used, other procedures, methodologies, or techniques known to those skilled in

20 the art may alternatively be used.

EXAMPLES

EXAMPLE 1

Stained extracted teeth were sectioned into two equal pieces. Each of the pieces was submerged into a peroxide solution or gel. One piece of each tooth was

25 submerged in peroxide alone, while the other was submerged in hydrogen peroxide with a catalyst, a hydrogen peroxide containing a modifier to raise the pH (either AMP or tris-Amino), or hydrogen peroxide

30 containing both the catalyst and the modifier. Three solutions were tested: (1) 3% hydrogen peroxide, (2) 6% hydrogen peroxide, and (3) 10% hydrogen peroxide. Two

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gels were tested: (1) a commercially available dentist-supervised bleaching gel containing hydrogen peroxide up to 7%, and (2) a commercially available dentist-supervised bleaching gel containing carbamide peroxide up to 20%. Two catalysts were used in the experiments, either a standard activated charcoal or Centaur (Calgon) activated charcoal. Samples were photographed after three minutes of exposure, and at several other time points.

10 When a catalyst was used, significant bleaching was noted after twelve minutes. The bleaching was comparable to between 21 and 30 hours of bleaching without the catalytic agent. It was noted that those gels containing large amounts of carbopol provided the
15 least amount of dental bleaching.

EXAMPLE 2

A catalytic agent was applied to a toothbrush by dipping a wet toothbrush into powdered catalytic agent, or by bonding activated charcoal to a toothbrush head
20 between the bristles. A whitening gel (Natural White) containing 1.5% hydrogen peroxide was applied to the toothbrush and the brush was used to clean a subject's teeth. A whitening effect was noted after one application of three minutes in duration. One subject
25 repeated the application of the whitening gel in the presence of the catalytic agent twice a day for three days. Significant whitening was noted following three days of application.

EXAMPLE 3

30 Liquid 3% hydrogen peroxide was mixed with a few drops a mint flavor. A small amount of activated charcoal catalytic agent was placed into a cup, and one-half teaspoon of the peroxide was added. This solution

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was used to bathe the teeth of subjects for sessions for three minutes of duration, carried out for twice a day over a period of several days. Visible whitening was noted after two days.

5 It is to be understood that this invention is not limited to the particular methodology, and that protocols, apparatus, models and reagents described as such may, of course, vary. It is also to be understood that the terminology used herein is for the purpose of
10 describing particular embodiments only, and is not intended to limit the scope of the present invention which will be limited only by the appended claims.

EXAMPLE 4

A specific formulation of the bleaching compound is as
15 follows:

Component	Concentration (percent by weight)
Hydrogen peroxide	10%
flavoring agent	1%
aloe vera	2%
20 potassium nitrate	1%
titanium dioxide	1%
sodium lauryl sulfate	1.5%
paste carrier	83.5%

In one embodiment, for use with the method of the
25 invention, a catalyst is prepared consisting of activated charcoal and AMP mixed in the ratio of 2:1. The formulation comprising the bleaching compound and the catalyst are combined at the time of use in the ratio of 10:1.

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In another embodiment, for use with a device of the invention, the formulation comprising the bleaching compound is placed on the toothbrush with a catalyst embedded into one or more of the bristles of the brush, or with a catalytic agent embedded in a fabric bonded to the head of the brush.

What is claimed is:

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1. A composition for whitening of teeth, comprising a therapeutically effective amount of a bleaching compound and a catalytic activator, wherein said catalytic activator is capable of catalyzing the reaction of said bleaching compound within ten minutes of contacting said catalytic activator with said bleaching compound.
2. The composition of claim 1, wherein the concentration of said bleaching compound is from about 3 to 40% by weight.
3. The composition of claim 2, wherein said bleaching compound is selected from the group consisting of carbamide peroxide, carbamyl peroxide, sodium percarbonate, perhydrol urea, and hydrogen peroxide.
4. The composition of claim 2, wherein the concentration of said bleaching compound is from about 3 to 12% by weight.
5. The composition of claim 4, wherein said bleaching compound comprises hydrogen peroxide.
6. The composition of claim 2, wherein the concentration of said bleaching compound is from about 10 to about 40% by weight.
7. The composition of claim 6, wherein said bleaching compound is selected from the group consisting of carbamide peroxide, carbamyl peroxide, sodium percarbonate, and perhydrol urea.
8. The composition of claim 1, wherein said catalytic activator is selected from the group consisting of activated charcoal, platinum, a platinum salt, copper, a copper salt, palladium, a palladium salt, silver, and a silver salt.

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9. The composition of claim 1, further comprising an abrasive agent.
10. The composition of claim 1, further comprising an agent for administering fluoride.
- 5 11. The composition of claim 1, further comprising a gel forming agent.
12. The composition of claim 1, further comprising a palliative ingredient for periodontal tissues.
13. The composition of claim 12, wherein said
10 palliative agent is selected from the group consisting of aloe, eugenol, and vitamin E.
14. The composition of claim 1, further comprising an ingredient to decrease tooth sensitivity.
15. The composition of claim 14, wherein said
15 ingredient to decrease tooth sensitivity is potassium nitrate.
16. A method for whitening teeth, comprising combining a bleaching compound with a catalytic agent, wherein the catalytic agent catalyzes the
20 reaction of a significant portion of the bleaching agent within ten minutes while in contact with said teeth.
17. The method of claim 16, wherein the concentration of said bleaching compound is from about 3 to 40%
25 by weight.
18. The method of claim 17, wherein said bleaching compound is selected from the group consisting of carbamide peroxide, carbamyl peroxide, sodium percarbonate, perhydrol urea, and hydrogen
30 peroxide.
19. The method of claim 16, wherein the concentration of said bleaching compound is from about 3 to 12% by weight.

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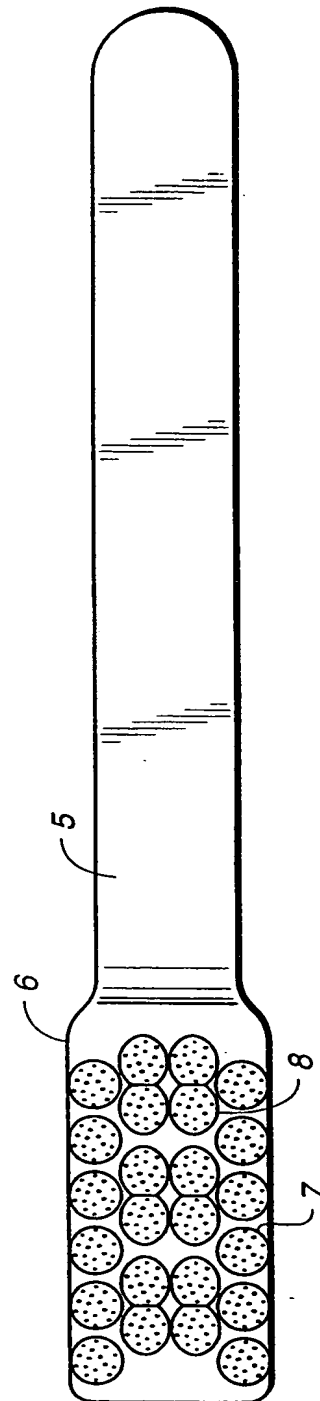
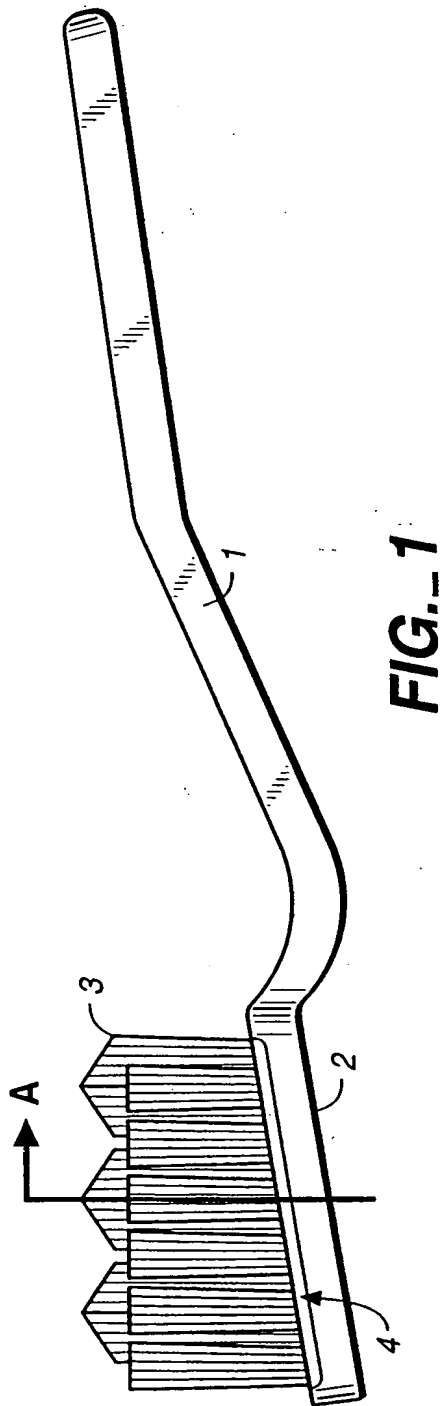
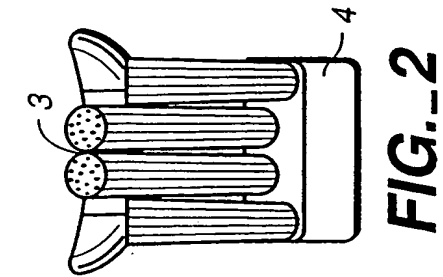
20. The method of claim 19, wherein said bleaching compound comprises hydrogen peroxide.
21. The method of claim 16, wherein the concentration of said bleaching compound is from about 10 to about 40% by weight.
22. The method of claim 21, wherein said bleaching compound is selected from the group consisting of carbamide peroxide, carbamyl peroxide, sodium percarbonate, and perhydrol urea.
23. The method of claim 16, wherein said combining is by the addition of water.
24. The method of claim 16, wherein said catalytic activator is selected from the group consisting of activated charcoal, platinum, a platinum salt, copper, a copper salt, palladium, a palladium salt, silver, and a silver salt.
25. A device for whitening teeth, said device comprising
a toothbrush comprising a head and a handle, said head having a plurality of bristles, wherein at least one bristle comprises a catalytic activator, and said handle comprising a reservoir for a bleaching compound and a means for dispensing said bleaching compound in close proximity to said bristles.
26. The device of claim 25, wherein said bleaching compound is selected from the group consisting of carbamide peroxide, carbamyl peroxide, sodium percarbonate, perhydrol urea, and hydrogen peroxide.
27. The device of claim 25, wherein said catalytic activator is selected from the group consisting of

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activated charcoal, platinum, a platinum salt, copper, a copper salt, palladium, a palladium salt, silver, and a silver salt.

28. A device for whitening teeth, said device
5 comprising;
a toothbrush comprising a head and a handle,
said head comprising an applicator and a
catalytic activator capable of catalyzing the
reaction of a bleaching compound applied to
10 said head.
29. The device of claim 28, wherein said head further
comprises a retaining means for holding a
bleaching agent in solid form.
30. The device of claim 28, wherein said applicator is
15 a plurality of bristles.
31. The device of claim 28, wherein said bleaching
compound is selected from the group consisting of
carbamide peroxide, carbamyl peroxide, sodium
percarbonate, perhydrol urea, and hydrogen
20 peroxide.
32. The device of claim 28, wherein said catalytic
activator is selected from the group consisting of
activated charcoal, platinum, a platinum salt,
copper, a copper salt, palladium, a palladium
25 salt, silver, and a silver salt.

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US98/10133**A. CLASSIFICATION OF SUBJECT MATTER**

IPC(6) :A46B 11/04; A61K 7/20, 7/22

US CL :424/53

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 424/53

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5,032,178 A (CORNELL) 16 July 1991, col. 4, lines 25-41.	1-6, 9, 11, 16-21, 23
X	US 5,437,858 A (HUNGERBACH et al) 01 August 1995, col. 1, line 28, col. 2, lines 19-41, and claims 1-4.	1-6, 8, 9, 10, 11, 14, 15
X,P	US 5,648,064 A (GAFFAR et al) 15 July 1997, see entire document.	1-7, 9-23, 25, 26, 28-31

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:	*T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
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Name and mailing address of the ISA/US
Commissioner of Patents and Trademarks
Box PCT
Washington, D.C. 20231

Facsimile No. (703) 305-3230

Authorized officer

ROBERT H. HARRISON

Telephone No. (703) 308-1235

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